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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,926	09/16/2003	Michael E. Benz	P-10909.00	2299
26813	7590	10/10/2006	EXAMINER	
MUETING, RAASCH & GEBHARDT, P.A. P.O. BOX 581415 MINNEAPOLIS, MN 55458			SERGENT, RABON A	
			ART UNIT	PAPER NUMBER
			1711	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/663,926

Applicant(s)

BENZ ET AL.

Examiner

Rabon Sergent

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 71-75 and 77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-70 and 76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See paragraph 3.</u>  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1711

1. Applicant's election with traverse of Group II, claims 1-70 and 76 in the reply filed on April 6, 2006 is acknowledged. The traversal is on the ground(s) that the inventions can be readily evaluated in one search without placing undue burden on the Examiner. This is not found persuasive because applicants have in no way established that undue burden would not be placed on the examiner if all of the inventions were searched. Given the reasons for distinctness between the groups and the fact that the respective groups are classified in different art areas, the search for one group will neither overlap nor be required for the other group; therefore, applicants' assertion that a search for one group will reveal art to the other is entirely without merit.

The requirement is still deemed proper and is therefore made FINAL.

2. The Election of Species Requirement set forth within paragraphs 6 and 7 of the Office action of September 28, 2005 has been withdrawn.

3. The Information Disclosure Statements filed January 12, 2004, January 30, 2004, March 1, 2004, June 3, 2004, February 7, 2005, November 22, 2005, December 15, 2005, February 28, 2006, and July 31, 2006 have been considered.

4. Claims 15, 34, and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have failed to define the term, "substantially free", as it pertains to ether, ester, and carbonate linkages. It cannot be determined what quantity of these linkages the

Art Unit: 1711

language provides for. The issue is further aggravated by the fact that applicants specifically recite at page 16 of the specification that polymers containing these linkages may be produced.

5. Claims 15, 34, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the absence of a definition of "substantially free", it cannot be determined what quantity of the ether, ester, and carbonate linkages may be present and still satisfy the claims.

6. Claims 1-12, 14-16, and 40-56 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polymers produced from the reaction of hydroxyl or amine functional compounds containing quaternary carbons and silicon groups, does not reasonably provide enablement for polymers produced by reacting other than hydroxyl or amine functional compounds containing quaternary carbons and silicon groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicants have failed to provide adequate guidance that would permit one to produce polymers having the claimed structures wherein the polymer results from other than the reaction of a hydroxyl or amine group. For example, applicants have failed to teach how to produce a polymer resulting from the reaction of an ethylenically unsaturated compound containing quaternary carbons and silicon groups; however, applicants' claims encompass such a polymer. In summation, applicants have only provided enablement for the production of polyureas, polyurethanes, polyamides, polyimides, epoxies, polyesters, polyacetals, polycarbonates, polysulfones, polyphosphates, and polyphosphonates, and the position is taken that one could not practice the

Art Unit: 1711

invention using other than amine or hydroxyl functional compounds without having to resort to undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 1711

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-70 and 76 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,984,700. Although the conflicting claims are not identical, they are not patentably distinct from each other because the R<sup>1</sup> groups within the claims of the patent encompass alkyl groups containing quaternary carbon groups.

9. Claims 1-70 and 76 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28, 30-34, 39, and 40 of copending Application No. 10/663,925. Although the conflicting claims are not identical, they are not patentably distinct from each other because the R<sup>1</sup> groups within the claims of the patent encompass alkyl groups containing quaternary carbon groups.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-70 and 76 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-46 and 48 of copending Application No. 11/133,627. Although the conflicting claims are not identical, they are not patentably distinct from each other because the R<sup>1</sup> groups within the claims of the patent encompass alkyl groups containing quaternary carbon groups.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1711

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-11, 14-16, and 40-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Deichert et al. ('506).



Art Unit: 1711

Patentees disclose polymers suitable for biomedical applications wherein the polymers possess structures containing quaternary carbons and silicon-containing groups that meet applicants' claimed structure. See abstract; column 1, lines 15-59; and columns 8-17.

13. Claims 1, 2, 4, 6-16, 40, 41, 43, 45-51, and 53-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Kato et al. ('325).

Patentees disclose polymers that possess structures containing quaternary carbons and silicon-containing groups that meet applicants' claimed structure. See abstract and columns 1-4. To the extent claimed, it is not seen that the language, "medical device", conveys any patentable distinction to the claims.

14. Claims 1-70 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs et al. ('254) or WO 01/07499 or WO 00/64971 or WO 99/50327 or WO 98/54242 or WO 99/03863, each in view of Pinchuk ('240) or Benz et al. (US 2003/0125499) or EP 821973.

Each of the primary references discloses polyurethane or polyurethane-urea polymers suitable for the production of medical devices, wherein the polymer is formed from a silicon-containing polyol or polyamine wherein the silicon-containing group corresponds to that claimed and further wherein R groups containing quaternary carbons are specifically disclosed as being suitable linkages within the polyol or polyamine. Note the disclosure that the alkyl or alkylene groups may be 1,1-dimethylpropyl, 1,1-dimethylbutyl, 2,2-dimethylbutyl, 3,3-dimethylbutyl, 1,2,2-trimethylpropyl, 1,1,2-trimethylpropyl, 2,2-dimethylpentyl, 3,3-dimethylpentyl, 4,4-dimethylpentyl, 1,1,2-trimethylbutyl, 1,1,3-trimethylbutyl, and 1,1,3,3-tetramethylbutyl.

15. The primary references fail to teach a specific preference for the incorporation of these quaternary carbon-containing groups within the silicon group-containing polyol or polyamine;



Art Unit: 1711

however, the advantages of incorporating such groups into polymer compositions to be used within medical applications was known at the time of invention. Pinchuk discloses that polymers having increased amounts of quaternary carbons are the most “medically” inert. See column 3, lines 60+ within Pinchuk (‘240) and page 3, lines 36-36 of EP 821,973. Benz et al. disclose biostable polyurethane polymers derived from quaternary carbon-containing polyols or polyamines, which are suitable for producing medical devices. See entire Benz et al. document. Therefore, in view of these secondary teachings disclosing the benefits of incorporating quaternary carbons into the polymer chain, the position is taken that one of ordinary skill, seeking a biostable polymer, would have been motivated to select and incorporate the disclosed quaternary-carbon containing groups of the primary reference as the R groups of the silicon-containing polyols or polyamines, so as to arrive at the instant invention. Furthermore, since the primary references establish the compatibility of the quaternary carbon-containing groups with the silicon-containing groups of the polyols or polyamines, the position is taken that it further would have been obvious to incorporate increased numbers of quaternary carbons or repeating quaternary carbon groups within the polyols or polyamines, so as to maximize the biostability of the final polymer.

16. Claims 1-16 and 40-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijs et al. (‘254) or WO 01/07499 or WO 00/64971 or WO 99/50327 or WO 98/54242 or WO 99/03863, each in view of Pinchuk (‘240) or Benz et al. (US 2003/0125499) or EP 821973 and further in view of Kennedy (‘973).

Each of the primary references discloses polyurethane or polyurethane-urea polymers suitable for the production of medical devices, wherein the polymer is formed from a silicon-

Art Unit: 1711

containing polyol or polyamine wherein the silicon-containing group corresponds to that claimed. See abstracts.

17. The primary references fail to provide a specific teaching regarding the incorporation of quaternary carbon-containing groups within the polymer; however, the advantages of incorporating such groups into polymer compositions to be used within medical applications was known at the time of invention. Pinchuk discloses that polymers having increased amounts of quaternary carbons are the most "medically" inert. See column 3, lines 60+ within Pinchuk ('240) and page 3, lines 36-36 of EP 821,973. Benz et al. disclose biostable polyurethane polymers derived from quaternary carbon-containing polyols or polyamines, which are suitable for producing medical devices. See entire Benz et al. document. Furthermore, Kennedy teaches the use of polyols that are in rich quaternary carbons to produce polyurethanes. See column 1, lines 6-31; column 5, and column 10, lines 24+ within Kennedy. Therefore, in view of these secondary teachings disclosing the medical benefits of incorporating quaternary carbons into the polymer chain and the known use of such quaternary carbon group-containing reactants to produce polyurethanes, the position is taken that one of ordinary skill, seeking a biostable polymer, would have been motivated to incorporate the polyol of Kennedy into the polymers of the primary references, so as to obtain a medically improved polymer having an elevated amount of quaternary-carbon containing groups. In view of the definitions of the variables for the structure of applicants' claims, the position is taken that there is no requirement that the claimed quaternary carbons and silicon-containing groups stem from a single reactant.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (571) 272-1079.

  
**RABON SERGENT**  
**PRIMARY EXAMINER**